

Appl. No. 09/931,562
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Reply to Office action of May 12, 2003

REMARKS/ARGUMENTS

Claims 15-19, 35-38, and 50-51 are canceled herewith without prejudice. Claims 39-47 were previously withdrawn, so that all the remaining claims are method claims. The Examiner's rejections of the remaining claims are discussed below.

I. Rejection over U.S. Patent 5,267,982 to Sylvanowicz.

The Examiner has rejected claims 1-38 and 48-67 over Sylvanowicz. This rejection is not understood for the following reason: The second sentence of this paragraph 6 of the Office action states "With regard to apparatus claims 1-7 it would appear that applicant in reciting the formation of the out of plane catheter configuration during a particular period of time has formulated the limitation in the claim as a statement of intended use."

Claims 1-7 are not "apparatus claims", and there is no reference in any of those claims (or in fact in any claim in the present application) to "out of plane configurations" or "out of plane" or, even, "plane".

Furthermore, this rejection is not understood since paragraph 6 ends as follows: "If not inherent". Applicant guesses that the Examiner was planning on continuing the discussion of the rejection, but is at a loss to determine what that discussion would have been had it been recited in the Office action.

Withdrawal of this rejection, and allowance of these claims is solicited.

To the extent that the Examiner is repeating the rejection made in previous Office actions to the claims of applicant's invention, applicant wishes to incorporate the discussions previously made of the Sylvanowicz reference. Specifically, with respect to claim 1, this claim requires, *inter alia*, that at least one of the catheter tube and the inner medical element be remotely controllable to form a curve in the distal end thereof. The claim also requires the step of shaping the distal end

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of the combination catheter, during imaging of the catheter tube and the inner medical element, by manipulating the distal end of the combination catheter by **remotely controlling the distal end of at least one of the catheter tube and the inner medical element to form a curve therein such that the distal end of the combination catheter takes a desired shape**" (Emphasis added).

Since neither the inner nor the outer tube in Sylvanowicz has any remote control means (e.g., a pull-wire), Sylvanowicz is incapable of performing the claimed method. Moreover, there is no hint in Sylvanowicz that such a remote control feature is needed. Therefore, there is no motivation to add to Sylvanowicz such a remote control. Sylvanowicz does not and cannot read upon claim 1. Claim 1 is allowable for all these reasons.

Claims 2-4 depend from claim 1 and are allowable therewith. In addition, claim 3 specifies that it is the inner medical element that is remotely controllable to assume curved configurations, and that the shaping step includes the operation of such remote control. Sylvanowicz has no such feature and is incapable of performing the claimed method. Claim 3 is allowable for this reason as well.

Claim 5 is an independent claim that specifies, like claim 3 that the inner medical element is manipulated by remote control to form the desired shape. As discussed above in connection with claims 1 and 3, Sylvanowicz completely lacks the remote control feature and hence is incapable of performing the claimed method.

Claim 6 depends from claim 5 and is allowable with that claim.

Claim 7 is an independent claim that requires that both the catheter tube and the inner medical element have curves (preformed in the case of the catheter tube, and either preformed or formed during the method in the case of the inner medical element) that are disposed from the

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extreme distal end of the corresponding element a distance no greater than three times the smaller radius of curvature of the curves in the catheter tube and the inner medical element. As explained in amendments to previous Office actions on parent applications, the curve in the outer catheter tube of Sylvanowicz does not fall within the required distance. Specifically, in Sylvanowicz the smaller radius of curvature is that of the inner medical element. The curve in the outer catheter tube of Sylvanowicz does not fall within a distance of three times the radius of curvature of the inner medical element curve. This feature is integral to the present invention, since it ensures that the curves of the inner medical element and the outer catheter tube interact in the shaping step so that, in the words of the claim, "the distal end of the combination catheter takes a desired shape in which the distal end of the inner medical element has a second radius of curvature." Sylvanowicz lacks this feature, and therefore cannot perform the claimed method. Claim 7 is allowable for all these reasons.

Claims 8-10 depend from claim 7 and are allowable therewith. In addition, claim 9 specifies that the inner medical element is remotely controllable to assume curved configurations, and that the shaping step includes manipulating the distal end of the inner medical element by remote control to form a curved configuration. As discussed above in connection with claims 1 and 3, Sylvanowicz lacks this feature and is, therefore, incapable of performing this method. Claim 9 is allowable for these reasons as well.

Claim 11 is a method claim that defines the distance of each curve (measured during the shaping step) in terms of the arc length of the smaller of the curves in the catheter tube and the inner medical element. Claim 11 is thus allowable over Sylvanowicz for the reasons set forth above in connection with claim 7.

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Claims 12-14 depend from claim 11 and are allowable for the same reasons as that claim. Moreover, claim 13 specifies that the shaping step includes remotely controlling the distal end of the inner medical element. As explained above in connection with claims 1 and 3, Sylvanowicz is incapable of performing this function. Claim 13 is allowable for this reason as well.

Claims 15-19 are cancelled herewith, without prejudice.

Claim 20 is an independent claim that requires, *inter alia*, that the outer catheter tube have remote control apparatus extending from the proximal end of the catheter tube for deflecting the distal end of the catheter tube, and that the shaping step include manipulating the distal end of the catheter tube by remote control to form a curved configuration. As discussed above in connection with claim 1, Sylvanowicz lacks such a remote control, has no motivation for adding a remote control feature, and hence is incapable of performing the claimed method. Claim 20 is allowable for all these reasons.

Claims 21 and 22 depend from claim 20 and are allowable therewith.

Claim 23 is an independent method claim that includes an inner medical element with remote control apparatus for selectively forming curved configurations of the inner medical element independent of the catheter tube, and requires the step of manipulating the distal end of the inner medical element by remote control to form a curved configuration. As discussed above in connection with claims 1 and 3, Sylvanowicz completely lacks this feature and is incapable of performing this function. Claim 23 is allowable for all these reasons.

Claims 24 and 25 depend from claim 23 and are allowable, *inter alia*, for the same reasons as that claim.

Claim 26 is an independent claim that specifies that the catheter tube has remote control apparatus extending from the proximal end of the catheter tube for deflecting the distal end of the

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catheter tube, and further specifies that the shape of the combination catheter is modified, at least in part, by manipulating the distal end of the catheter tube by remote control to form a curved configuration. As discussed in connection with claim 1, Sylvanowicz lacks this feature and is incapable of performing this function. Claim 26 is allowable for all these reasons.

Claim 27 and 28 depend from claim 26 and are allowable therewith.

Claim 29 is an independent claim that, like claim 7, requires that the curves in the inner medical element and the catheter tube, during use, be disposed a distance from the ends of the corresponding elements no greater than three times the smallest radius of curvature of the inner medical element curve or the catheter tube curve. Again, as discussed above, Sylvanowicz lacks this feature. Claim 29 is allowable for all these reasons.

Claims 30 and 31 depend from claim 29 and are allowable along with that claim.

Claim 32 is an independent claim like claim 29, but which specifies the required distance in terms of arc length. As discussed in connection with claim 11, this is totally absent from Sylvanowicz. In fact, Sylvanowicz teaches away from this. If the outer catheter tube had its curve within three arc lengths of the inner medical element curve from its distal end, the Sylvanowicz catheter would not fit properly around the aortic arch. Claim 32 is allowable for all these reasons.

Claims 33 and 34 depend from claim 32 and are allowable therewith.

Claims 35-38 are cancelled herewith, without prejudice.

Claim 48 is an independent claim that includes the "smaller radius of curvature" feature discussed above in connection with claim 7. Claim 48 is allowable for the same reasons as that claim.

Similarly, claim 49 is an independent claim that includes the "smaller arc length" feature of claim 11. This claim is, therefore, allowable for the same reasons as claim 11.

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Claims 50 and 51 are cancelled herewith, without prejudice.

Claim 52 is an independent claim that includes the step of manipulating the distal end of at least one of the inner medical element and the catheter tube by remote control to form a curved configuration. As discussed above in connection with claim 1, Sylvanowicz does not have this feature, and cannot perform this function. Claim 52 is allowable for all these reasons.

Claims 53-55 depend from claim 52 and are allowable therewith. In addition, claim 54 requires that the inner medical element be remotely controlled during shaping to assume a curved configuration. As discussed above in connection with claim 3, Sylvanowicz also lacks this specific feature. Claim 54 is allowable for this reason as well.

Claim 56 is an independent claim that requires at least one of the catheter tube and the inner medical element to be remotely controllable to form a curve in the distal end thereof. As discussed in connection with claim 1, Sylvanowicz does not have this feature, and provides no motivation for it. Claim 56 is allowable for all these reasons.

Claims 57-59 depend from claim 56 and are allowable therewith. Moreover, claim 58 provides that the inner medical element is remotely controllable. That feature, as explained above, is absent from Sylvanowicz.

Claim 60 is an independent claim that also specifies that at least one of the catheter tube and the inner medical element are remotely controllable to form a curve in the distal end thereof. Claim 60 is, therefore, allowable for essentially the same reasons as claims 1 and 56.

Claims 61-63 depend from claim 60 and are allowable for the same reasons as that claim. Claim 62 further requires that the inner medical element be remotely controllable to assume curved configurations, which feature is also absent from Sylvanowicz.

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Claim 64 is an independent claim requiring that the catheter tube be remotely controllable to form a curve in the distal end thereof. As discussed in connection with claim 1, this feature is not found in or suggested by Sylvanowicz.

Claims 65-67 depend from claim 64 and are allowable therewith. Claim 66 also specifies that the inner medical element is remotely controllable to assume curved configurations. That feature is absent from Sylvanowicz, as discussed above.

II. Rejection over U.S. Patents 4,474,174 to Petruzzi and 5,109,830 to Cho.

Much of the rejection based upon Petruzzi and Cho is not understood, since it appears to be directed to an "out of plane" feature that does not appear in any of the claims in this case. Moreover, the Examiner refers to the "bends in the Petruzzi catheter as shown in figure 11" (with reference to the three times the smallest radius of curvature feature) when Fig. 11 of Petruzzi clearly shows only one bend. To the extent that the rejection is understood, it is fatally flawed by the admitted absence of imaging in Petruzzi, and the admitted absence of remote control pull wires in Cho. The Examiner takes the position that these features could be added to either reference, but where is the motivation for that? Petruzzi discloses an endoscope, which is defined as "an instrument for visualizing the interior of a hollow organ." Endoscopes such as that shown in Petruzzi have no need for the fluoroscopic imaging that is the subject of the present claims to determine location in the body. There is, therefore, no motivation in this art for adding an unnecessary feature (fluoroscopic imaging) to Petruzzi. The rejections based upon Petruzzi cannot be correct. Similarly, where is there motivation in this art to modify Cho by adding pullwires? That would add expense, and reduce the operational lumen of the device, to solve a problem that Cho does not even recognize. Cho appears to work well for its intended purpose. Why would anyone make it more expensive and reduce its lumen size? Only the present

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invention answers that question—to provide the vast number of shapes that the presently claimed invention makes possible. The combination of Petruzzi and Cho is based solely on hindsight, and is improper. This entire rejection should be withdrawn.

Turning to the claims, claim 1 requires that at least one of the inner medical element and outer catheter tube be remotely controllable. Since neither the inner nor the outer tube in Cho has any remote control means (e.g., a pull-wire), Cho is incapable of performing the claimed method. Moreover, there is no hint in Cho that such a remote control feature is needed. Therefore, there is no motivation to add to Cho such a remote control. Cho does not and cannot read upon claim 1. Moreover, Petruzzi also fails to show the elements of claim 1. Claim 1 requires imaging the catheter tube and the inner medical element while the tube and medical element are disposed in the human body. It also requires verifying the desired shape (after such a shape is formed) by imaging the catheter tube and the inner medical element. Petruzzi completely lacks these features. Nor, as discussed above, is there any reason in this art to combine the features of Petruzzi and Cho. Only the present invention teaches such a combination. Claim 1 is allowable for all these reasons.

Claims 2-4 depend from claim 1 and are allowable therewith. In addition, claim 2 provides that the imaging is done by fluoroscopy. Petruzzi completely lacks such a feature. And claim 3 specifies that it is the inner medical element that is remotely controllable to assume curved configurations, and that the shaping step includes the operation of such remote control. Cho has no such feature and is incapable of performing the claimed method. Claims 2 and 3 are allowable for these reasons as well.

Claim 5 is an independent claim that specifies, like claim 3 that the inner medical element is manipulated by remote control to form the desired shape. As discussed above in connection

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with claims 1 and 3, Cho completely lacks the remote control feature and hence is incapable of performing the claimed method. Claim 5 also requires the imaging steps discussed above in connection with claim 1. Petruzzi completely lacks those features. Since there is no motivation to combine Cho and Petruzzi, claim 5 is allowable over this art.

Claim 6 depends from claim 5 and is allowable with that claim. It also provides that the imaging is done by fluoroscopy.

Claim 7 is an independent claim that requires that the catheter tube have a preformed curve (and that the inner medical element also have a curve, either preformed or formed during the method) that is disposed from the extreme distal end of the catheter tube a distance no greater than three times the smaller radius of curvature of the curves in the catheter tube and the inner medical element. As explained in amendments to previous Office actions on parent applications, the catheter tube in Cho (the outer element) is straight, not curved, so it cannot show or suggest this feature. Cho lacks this feature, and therefore cannot perform the claimed method. Moreover, claim 7 has the imaging steps discussed above in connection with claim 1. Petruzzi completely lacks those, and there is no motivation to combine Cho and Petruzzi. Claim 7 is allowable for all these reasons.

Claims 8-10 depend from claim 7 and are allowable therewith. Claim 8 specifies that the imaging is done by fluoroscopy. Petruzzi completely lacks this feature. In addition, claim 9 specifies that the inner medical element is remotely controllable to assume curved configurations, and that the shaping step includes manipulating the distal end of the inner medical element by remote control to form a curved configuration. As discussed above in connection with claims 1 and 3, Cho lacks this feature and is, therefore, incapable of performing this method. Claims 8 and 9 are allowable for these reasons as well.

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Claim 11 is a method claim that defines the distance of each curve (measured during the shaping step) in terms of the arc length of the smaller of the curves in the catheter tube and the inner medical element. Cho has no curve in its outer catheter, so Claim 11 is thus allowable over Cho for the reasons set forth above in connection with claim 7. Moreover, claim 11 requires the imaging steps discussed above in connection with claim 1, which Petruzzi lacks. There is no motivation to combine Cho and Petruzzi. Therefore, claim 11 is allowable for all these reasons.

Claims 12-14 depend from claim 11 and are allowable for the same reasons as that claim. Claim 12 requires that the imaging be done by fluoroscopy, which is completely absent from Petruzzi. And, claim 13 specifies that the shaping step includes remotely controlling the distal end of the inner medical element. As explained above in connection with claims 1 and 3, Cho is incapable of performing this function. Claims 12 and 13 are allowable for these reasons as well.

Claims 15-19 are cancelled herewith, without prejudice.

Claim 20 is an independent claim that requires, *inter alia*, the steps of imaging the combination catheter while it is in the human body, and modifying the shape of the distal end of the combination catheter during imaging. As discussed above, Petruzzi completely lacks such imaging steps (and has no need for them). Moreover, claim 20 specifies that the outer catheter tube has remote control apparatus extending from the proximal end of the catheter tube for deflecting the distal end of the catheter tube, and that the shaping step include manipulating the distal end of the catheter tube by remote control to form a curved configuration. As discussed above in connection with claim 1, Cho lacks such a remote control, has no motivation for adding a remote control feature, and hence is incapable of performing the claimed method. Claim 20 is allowable for all these reasons.

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Claims 21 and 22 depend from claim 20 and are allowable therewith. Claim 22, in addition, requires that the imaging be done fluoroscopically, which feature is totally absent from Petrucci.

Claim 23 is an independent method claim that includes an inner medical element with remote control apparatus for selectively forming curved configurations of the inner medical element independent of the catheter tube, and requires the step of manipulating the distal end of the inner medical element by remote control to form a curved configuration. It also requires the imaging steps described above in connection with claim 20. Petrucci lacks the imaging steps. And, as discussed above in connection with claims 1 and 3, Cho completely lacks the remote control feature and is incapable of performing this function. Claim 23 is allowable for all these reasons. •

Claims 24 and 25 depend from claim 23 and are allowable for the same reasons as that claim. In addition, claim 25 requires that the imaging be done fluoroscopically. Petrucci, as discussed above, does not have such a feature.

Claim 26 is an independent claim that requires imaging steps like those in claim 20 and further specifies that the shape of the combination catheter is modified, at least in part, by manipulating the distal end of the catheter tube by remote control to form a curved configuration. As discussed in connection with claim 1, Cho lacks the remote control feature and is incapable of performing this function. Similarly, Petrucci lacks the imaging requirements of the claim. Claim 26 is allowable for all these reasons.

Claim 27 and 28 depend from claim 26 and are allowable therewith. Claim 28 further requires that the imaging be done fluoroscopically.

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Claim 29 is an independent claim that, like claim 7, requires that the curves in the inner medical element and the catheter tube, during use, be disposed a distance from the ends of the corresponding elements no greater than three times the smallest radius of curvature of the inner medical element curve or the catheter tube curve. Again, as discussed above, Cho completely lacks this feature since the outer element of Cho is straight. Claim 29 also requires imaging steps like those of claim 20, which steps are completely absent from Petruzzi. There is no motivation to combine Cho and Petruzzi, so claim 29 is allowable for all these reasons.

Claims 30 and 31 depend from claim 29 and are allowable along with that claim. Claim 31 also requires that the imaging be done fluoroscopically.

Claim 32 is an independent claim like claim 29, but which specifies the required distance in terms of arc length. As discussed in connection with claim 11, this is totally absent from Cho. Claim 32 also requires imaging steps like those discussed in connection with claim 20, which steps are totally absent from Petruzzi. There is no motivation to combine Cho and Petruzzi, so claim 32 is allowable for all these reasons.

Claims 33 and 34 depend from claim 32 and are allowable therewith. Claim 34 further specifies that the imaging is done fluoroscopically.

Claims 35-38 are cancelled herewith, without prejudice.

Claim 48 is an independent claim that includes the "smaller radius of curvature" feature discussed above in connection with claim 7. It also includes imaging steps like those described above in connection with claim 1. Claim 48 is allowable for the same reasons as those claims.

Similarly, claim 49 is an independent claim that includes the "smaller arc length" feature of claim 11, and imaging steps like claim 1. This claim is, therefore, allowable for the same reasons as claim 1 and 11.

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Claims 50 and 51 are cancelled herewith, without prejudice.

Claim 52 is an independent claim that includes the step of manipulating the distal end of at least one of the inner medical element and the catheter tube by remote control to form a curved configuration. As discussed above in connection with claim 1, Cho does not have this feature, and cannot perform this function. Claim 52 also requires imaging steps just as those discussed in connection with claim 1. These imaging steps are completely absent from Petruzzi. Since there is no motivation to combine Cho and Petruzzi, claim 52 is allowable for all these reasons.

Claims 53-55 depend from claim 52 and are allowable therewith. Claim 53 specifies that the imaging is done by fluoroscopy, which feature is absent from Petruzzi. In addition, claim 54 requires that the inner medical element be remotely controlled during shaping to assume a curved configuration. As discussed above in connection with claim 3, Cho also lacks this specific feature. Claims 53 and 54 are allowable for these reasons as well.

Claim 56 is an independent claim that requires at least one of the catheter tube and the inner medical element to be remotely controllable to form a curve in the distal end thereof. As discussed in connection with claim 1, Cho does not have this feature, and provides no motivation for it. Claim 56 also specifies imaging steps like those discussed above in connection with claim 1. Petruzzi completely lacks such steps. Claim 56 is allowable for all these reasons. Claims 57-

59 depend from claim 56 and are allowable therewith. Claim 57 provides that the imaging is done by fluoroscopy. Petruzzi lacks such a feature. Moreover, claim 58 provides that the inner medical element is remotely controllable. That feature, as explained above, is absent from Cho. Claims 57 and 58 are allowable for these reasons as well.

Claim 60 is an independent claim that also specifies that at least one of the catheter tube and the inner medical element are remotely controllable to form a curve in the distal end thereof.

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It also includes imaging steps like those discussed in connection with claim 1. Claim 60 is, therefore, allowable for essentially the same reasons as claims 1 and 56.

Claims 61-63 depend from claim 60 and are allowable for the same reasons as that claim. Claim 61 provides that the imaging is done by fluoroscopy, which is absent from Petruzzi. And claim 62 further requires that the inner medical element be remotely controllable to assume curved configurations, which feature is also absent from Cho. Claims 61 and 62 are also allowable for these reasons.

Claim 64 is an independent claim requiring that the catheter tube be remotely controllable to form a curve in the distal end thereof. As discussed in connection with claim 1, this feature is not found in or suggested by Cho. Claim 64 also requires imaging steps like those discussed above in connection with claim 1. Such a feature is neither disclosed nor taught by Petruzzi. Claim 64 is allowable for all these reasons.

Claims 65-67 depend from claim 64 and are allowable therewith. Claim 65 requires that the imaging be done by fluoroscopy, which feature is absent from Petruzzi. Claim 66 also specifies that the inner medical element is remotely controllable to assume curved configurations. That feature is absent from Cho, as discussed above. Claims 65 and 66 are allowable for these reasons as well.

III. Rejection over U.S. Patent 4,430,083 to Ganz et al ("Ganz")

The Examiner has rejected claims 1-38 and 48-67 over Ganz. This rejection is not understood because the rejection makes several references to "plane" and "out of plane". Since none of the claims in this case are directed to such a feature, the basis of the rejection is not understood. To the extent that Ganz is understood, applicant makes the following comments:

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Claim 1 requires, *inter alia*, that at least one of the catheter tube and the inner medical element be remotely controllable to form a curve in the distal end thereof. The claim also requires the step of shaping the distal end of the combination catheter, during imaging of the catheter tube and the inner medical element, by manipulating the distal end of the combination catheter by remotely controlling the distal end of at least one of the catheter tube and the inner medical element to form a curve therein such that the distal end of the combination catheter takes a desired shape" (Emphasis added).

Since neither the outer tube nor the angiography catheter in Ganz has any remote control means (e.g., a pull-wire), Ganz is incapable of performing the claimed method. Moreover, there is no hint in Ganz that such a remote control feature is needed. Therefore, there is no motivation to add to Ganz such a remote control. Ganz does not and cannot read upon claim 1. Claim 1 is allowable for all these reasons.

Claims 2-4 depend from claim 1 and are allowable therewith. In addition, claim 3 specifies that it is the inner medical element that is remotely controllable to assume curved configurations, and that the shaping step includes the operation of such remote control. Ganz has no such feature and is incapable of performing the claimed method. Claim 3 is allowable for this reason as well.

Claim 5 is an independent claim that specifies, like claim 3 that the inner medical element is manipulated by remote control to form the desired shape. As discussed above in connection with claims 1 and 3, Ganz completely lacks the remote control feature and hence is incapable of performing the claimed method.

Claim 6 depends from claim 5 and is allowable with that claim.

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Claim 7 is an independent claim that requires, *inter alia*, shaping the distal end of the combination catheter by manipulating the distal end of the combination catheter such that it takes a desired shape, the desired shape being one of a plurality of possible shapes the distal end of the combination catheter can take. Claim 7 also requires that the inner medical element take a shape in which the distal end of the inner medical element is curved. Ganz has two embodiments. In the first, the inner catheter I 1 has a straight distal end portion 47 (see col. 6, line 47), while in the second the distal end portion 47a has two orientation bend sections 101 and 103 that ensure that the inner catheter automatically orients to a single, predetermined position with respect to the outer catheter tube (see col. 6, lines 52-57). See also the following passage from col. 2, line 61ff:

"For catheters of this invention which have a passage-seeking bend section, it is important that this bend section emerge from the distal opening of the angiography catheter at the correct angular orientation. With this invention, orientation is automatically provided as the catheter is passed through the angiography catheter by providing the inner catheter with at least one orientation bend section in its distal end portion. This orientation bend section cooperates with a bend section of the angiography catheter to angularly orient the passage-seeking bend section." (Emphasis added).

Thus, with Ganz, the inner catheter either has a straight distal end (which excludes it from the invention of claim 7) or it is capable of being manipulated into only one desired shape (which also excludes it, since claim 7 requires a plurality of possible shapes). For all these reasons, claim 7 is allowable over Ganz.

Claims 8-10 depend from claim 7 and are allowable therewith. In addition, claim 9 specifies that the inner medical element is remotely controllable to assume curved configurations, and that the shaping step includes manipulating the distal end of the inner medical element by

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remote control to form a curved configuration. As discussed above in connection with claims 1 and 3, Ganz lacks this feature and is, therefore, incapable of performing this method. Claim 9 is allowable for these reasons as well.

Claim 11 is a method claim that also requires that the desired shape be formed from a plurality of possible shapes. Claim 11 is thus allowable over Ganz for the reasons set forth above in connection with claim 7.

Claims 12-14 depend from claim 11 and are allowable for the same reasons as that claim. Moreover, claim 13 specifies that the shaping step includes remotely controlling the distal end of the inner medical element. As explained above in connection with claims 1 and 3, Ganz is incapable of performing this function. Claim 13 is allowable for this reason as well. Claims 15-19 are cancelled herewith, without prejudice.

Claim 20 is an independent claim that requires, *inter alia*, that the outer catheter tube have remote control apparatus extending from the proximal end of the catheter tube for deflecting the distal end of the catheter tube, and that the shaping step include manipulating the distal end of the catheter tube by remote control to form a curved configuration. As discussed above in connection with claim 1, Ganz lacks such a remote control, has no motivation for adding a remote control feature, and hence is incapable of performing the claimed method. Claim 20 is allowable for all these reasons.

Claims 21 and 22 depend from claim 20 and are allowable therewith.

Claim 23 is an independent method claim that includes an inner medical element with remote control apparatus for selectively forming curved configurations of the inner medical element independent of the catheter tube, and requires the step of manipulating the distal end of the inner medical element by remote control to form a curved configuration. As discussed above

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in connection with claims 1 and 3, Ganz completely lacks this feature and is incapable of performing this function. Claim 23 is allowable for all these reasons.

Claims 24 and 25 depend from claim 23 and are allowable, *inter alia*, for the same reasons as that claim.

Claim 26 is an independent claim that specifies that the catheter tube has remote control apparatus extending from the proximal end of the catheter tube for deflecting the distal end of the catheter tube, and further specifies that the shape of the combination catheter is modified, at least in part, by manipulating the distal end of the catheter tube by remote control to form a curved configuration. As discussed in connection with claim 1, Ganz lacks this feature and is incapable of performing this function. Claim 26 is allowable for all these reasons.

Claim 27 and 28 depend from claim 26 and are allowable therewith.

Claim 29 is an independent claim that, like claim 7, requires that the shape of the distal end be modified to form a desired shape, said desired shape being one of a plurality of possible shapes the distal end of the combination catheter can take. As discussed above in connection with claim 7, Ganz lacks this feature. Claim 29 is allowable for all these reasons.

Claims 30 and 31 depend from claim 29 and are allowable along with that claim.

Claim 32 is an independent claim like claim 29 which includes the plurality of shapes feature of claim 7. This is totally absent from Ganz. In fact, Ganz teaches away from this. Ganz is deliberately achieving a single shape, not selecting a shape from a plurality of possible shapes. The presently claimed invention defeats the purpose of Ganz. Claim 32 is allowable for all these reasons.

Claims 33 and 34 depend from claim 32 and are allowable therewith.

Claims 35-38 are cancelled herewith, without prejudice.

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Claims 48-50 are independent claims that all include the "plurality of possible shapes" feature discussed above in connection with claim 7. Claims 48-50 are allowable for the same reasons as that claim.

Claims 50 and 51 are cancelled herewith, without prejudice.

Claim 52 is an independent claim that includes the step of manipulating the distal end of at least one of the inner medical element and the catheter tube by remote control to form a curved configuration. As discussed above in connection with claim 1, Ganz does not have this feature, and cannot perform this function. It also includes the "plurality of possible shapes" feature of claim 7. Claim 52 is allowable for all these reasons.

Claims 53-55 depend from claim 52 and are allowable therewith. In addition, claim 54 requires that the inner medical element be remotely controlled during shaping to assume a curved configuration. As discussed above in connection with claim 3, Ganz also lacks this specific feature. Claim 54 is allowable for this reason as well.

Claim 56 is an independent claim that requires at least one of the catheter tube and the inner medical element to be remotely controllable to form a curve in the distal end thereof. As discussed in connection with claim 1, Ganz does not have this feature, and provides no motivation for it. Claim 56 also includes the "plurality of possible shapes" feature of claim 7. Claim 56 is allowable for all these reasons.

Claims 57-59 depend from claim 56 and are allowable therewith. Moreover, claim 58 provides that the inner medical element is remotely controllable. That feature, as explained above, is absent from Ganz.

Claim 60 is an independent claim that also specifies that at least one of the catheter tube and the inner medical element are remotely controllable to form a curve in the distal end thereof.

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Claim 60 also includes the "plurality of possible shapes" feature of claim 7. Claim 60 is, therefore, allowable for essentially the same reasons as claims 1, 7 and 56.

Claims 61-63 depend from claim 60 and are allowable for the same reasons as that claim.

Claim 62 further requires that the inner medical element be remotely controllable to assume curved configurations, which feature is also absent from Ganz.

Claim 64 is an independent claim requiring that the catheter tube be remotely controllable to form a curve in the distal end thereof. As discussed in connection with claim 1, this feature is not found in or suggested by Ganz. Claim 64 also specifies the "plurality of possible shapes" feature of claim 7. That feature is also absent from Ganz, and in fact Ganz teaches away from that feature.

Claims 65-67 depend from claim 64 and are allowable therewith. Claim 66 also specifies that the inner medical element is remotely controllable to assume curved configurations. That feature is absent from Ganz, as discussed above.

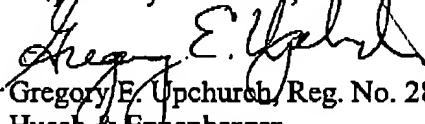
IV. REJECTION OVER U.S. PATENT 5,109,830 TO CHO

This rejection is fully discussed in section II above, discussing both Petruzzi and Cho.

V. CONCLUSION

In view of the above, favorable reconsideration and a Notice of Allowability of claims 1-14, 20-34, 48, 49 and 52-67 (all the claims remaining in the case) is solicited.

Respectfully submitted,


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